

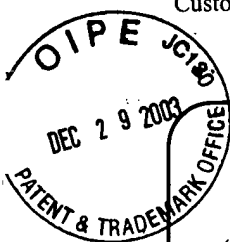
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PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/632,281
Filing Date	August 1, 2003
First Named Inventor	William Leon Elliott
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC20553A

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to a Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): Return Postcard
Remarks _____		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Rosanne Goodman Reg. No. 32,534
Signature	<i>Rosanne Goodman</i>
Date	<i>12/24/03</i>

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date 12-24-03

Typed or printed	Cindy Malocha
Signature	<i>Cindy Malocha</i>
Date	<i>12-24-03</i>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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USPTO Fax No.



PC20553A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : WILLIAM LEON ELLIOTT, ET AL.      EXAMINER :  
SERIAL NO : 10/632,281      ART UNIT : 1614  
FILED : AUGUST 1, 2003      PAPER NO :  
FOR : THERAPEUTIC COMBINATIONS OF erb B KINASE INHIBITORS AND  
ANTINEOPLASTIC THERAPIES

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 CFR 1.97 ET SEQ**

December 24, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants herein make available to the U.S. Patent and Trademark Office a copy of PTO/SB/08A and PTO/SB/08B, which lists the references cited by the applicants, copies of which are enclosed.

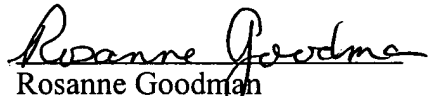
The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 CFR 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B be included in the "References Cited" portion of any patent issuing from this application (MPEP 1302.12).

A prompt and favorable response is earnestly solicited.

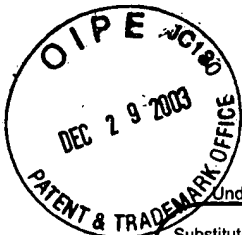
Respectfully submitted,

Dated: 12/24/03

  
Rosanne Goodman  
Registration No. 32,534  
Warner-Lambert Company LLC  
2800 Plymouth Road  
Ann Arbor, MI 48105  
Telephone: (734) 622-4182  
Facsimile: (734) 622-1553

Enclosures





PTO/SB/08B (08-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/632,281
Filing Date	August 1, 2003
First Named Inventor	William Leon Elliott
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC20553A

Sheet	2	of	3
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		PCT International Search Report, PCT/IB03/03388	
		Ciardiello and Tortora, "Anti-epidermal growth factor receptor drugs in cancer therapy", Expert Opinion on Investigational Drugs, Vol. 11, No. 6, 2002, pages 755-768	
		Erllichman et al., "The HER Tyrosine Kinase Inhibitor CI1033 Enhances Cytotoxicity of 7-Ethyl-10-hydroxycamptothecin and Topotecan by Inhibiting Breast Cancer Resistance Protein-mediated Drug Efflux", Cancer Research, Vol. 61, No. 2, 2001, pages 739-748	
		Giese et al., "Evidence for epidermal growth factor receptor-enhanced chemosensitivity in combinations of cisplatin and the new irreversible tyrosine kinase inhibitor CI-1033", Anti-Cancer Drugs, Vol. 12, No. 8, 2001, pages 683-690	
		Nelson and Fry, "Akt, MAPK (Erk1/2), and p38 Act in Concert to Promote Apoptosis in Response to ErbB Receptor Family Inhibition", The Journal of Biological Chemistry, Vol. 276, No. 18, 2001, pages 14842-14847	
		Rao et al., "Radiosensitization of Human Breast Cancer Cells by a Novel ErbB Family Receptor Tyrosine Kinase Inhibitor", Int. J. Radiation Oncology Biol. Phys., Vol. 48, No. 5, 2000, pages 1519-1528	
		Zhang et al., "Apoptotic Sensitization in Non-Small Cell Lung Cancer Cells Through Tyrosine Kinase Inhibition: Possible Role for Cytokine Signaling and Non-Receptor Tyrosine Kinases as Regulators of Caspase Activation and NSCLC Cell Survival", Proceedings of the American Association for Cancer Research, Vol. 42, 2001, page 131	
		Ciardiello et al., "Antitumor Effect and Potentiation of Cytotoxic Drugs Activity in Human Cancer Cells by ZD-1839 (Iressa), an Epidermal Growth Factor Receptor-selective Tyrosine Kinase Inhibitor", Clinical Cancer Research, Vol. 6, No. 5, 2000, pages 2053-2063	
		Slischenmyer et al., "CI-1033, a Pan-erbB Tyrosine Kinase Inhibitor", Seminars in Oncology, Vol. 28, No. 5, Suppl. 16, 2001, pages 80-85	
		Belani et al., "Phase I Trial, Including Pharmacokinetic and Pharmacodynamic Correlations, of Combination Paclitaxel and Carboplatin in Patients With Metastatic Non-Small-Lung Cancer", Journal of Clinical Oncology, Vol. 17, No. 2, 1999, pages 676-684	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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	<b>Filing Date</b>	August 1, 2003
	<b>First Named Inventor</b>	William Leon Elliott
	<b>Art Unit</b>	1614
	<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	PC20553A	

Sheet	3	of	3
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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Shin et al., "Epidermal Growth Factor Receptor-targeted Therapy with C225 and Cisplatin in Patients with Head and Neck Cancer", Clinical Cancer Research, Vol. 7, 2001, pages 1204-1213	
		Sawyers, "Rational therapeutic intervention in cancer: kinases as drug targets", Current Opinion in Genetics & Development, Vol. 12, 2002, pages 111-115	
		Atallah et al., "Chronic Myelogenous Leukemia in T Cell Lymphoid Blastic Phase Achieving Durable Complete Cytogenetic and Molecular Remission with Imatinib Mesylate (STI571; Gleevec) Therapy", Cancer, Vol. 94, No. 11, 2002, pages 2996-2999	
		Slamon et al., "Use of Chemotherapy Plus a Monoclonal Antibody Against HER2 for Metastatic Breast Cancer That Overexpresses HER2", The New England Journal of Medicine, Vol. 344, No. 11, 2001, pages 783-792	
		Ye et al., "Augmentation of a humanized Anti-HER2 mAb 4D5 induced growth inhibition by a human-mouse chimeric anti-EGF receptor mAb C225", Oncogene, Vol. 18, 1999, pages 731-738	
		Ciardiello et al., "Antitumor Activity of Sequential Treatment with Topotecan and Anti-Epidermal Growth Factor Receptor Monoclonal Antibody C225", Clinical Cancer Research, Vol. 5, 1999, pages 909-916	
		Milas et al., "In Vivo Enhancement of Tumor Radioresponse by C225 Antiepidermal Growth Factor Receptor Antibody", Clinical Cancer Research, Vol. 6, 2000, pages 701-708	
		Inoue et al., "Paclitaxel Enhances the Effects of the Anti-Epidermal Growth Factor Receptor Monoclonal Antibody ImClone C225 in Mice with Metastatic Human Bladder Transitional Cell Carcinoma", Clinical Cancer Research, Vol. 6, 2000, pages 4874-4884	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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